



## Getting the most out of pragmatic trials – beyond intention to treat

Dr Eleanor Murray

School of Public Health, Boston University

### Wednesday, 20<sup>th</sup> November 2019

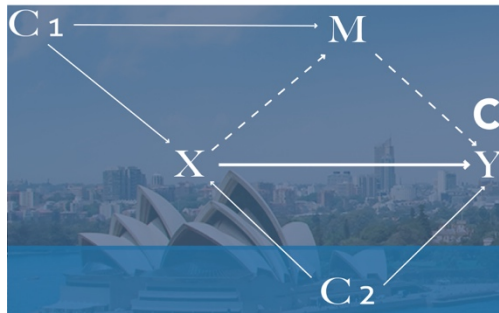
#### Day 1

8.30am	Registration opens
9.00am	Welcome & housekeeping – A/Prof James McAuley
9.10am	What is a pragmatic trial?
	Asking good causal questions
10.30am	Morning tea break
11.00am	Understanding causal graphs
12.30pm	Lunch break
1.30pm	Intention-to-treat effects, but better
	Per-protocol effects, done right
3.00pm	Afternoon tea break
3.30pm	Guidelines for causal inference from pragmatic trials
5.00pm	End of Day 1

### Thursday, 21st November 2019

#### Day 2 - Morning

9.00am	Practicum: Estimating causal effects from pragmatic trials with survival outcomes
10.30am	Morning tea break
11.00am	Practicum: Estimating causal effects from pragmatic trials with survival outcomes <i>continued</i>
12.30pm	Lunch break



Miguel Hernán & Eleanor Murray  
**Causal Inference from pragmatic trials  
 and observational data**

20 - 22 November 2019

## Causal inference from observational data: Learning what works

Professor Miguel Hernán

Departments of Epidemiology and Biostatistics,  
 Harvard T.H. Chan School of Public Health

Thursday, 21<sup>st</sup> November 2019

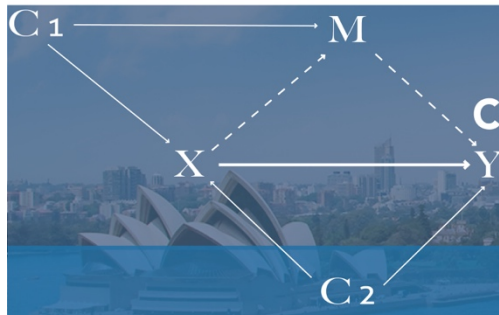
Day 2 – Afternoon

12.30pm	Lunch break
1.30pm	Introduction: Asking causal questions <i>Case study #1: Hormone therapy and coronary heart disease</i>
	Emulating the target trial <i>Case study #2: Statins and mortality in cancer patients</i>
3.00pm	Afternoon tea break
3.30pm	Choosing time zero <i>Case study #3: Screening colonoscopy and colorectal cancer</i>
5.00pm	End of Day 2

Friday, 22<sup>nd</sup> November 2019

Day 3

9.00am	Confounding adjustment: emulating randomization <i>Case study #4: Statins and coronary heart disease</i>
10.30am	Morning tea break
11.00am	Treatment strategies <i>Case study #5: Epoetin dosing and mortality in hemodialysis patients</i>
	Sustained treatment strategies
12.30pm	Lunch break
1.30pm	Strategies with a grace period <i>Case study #6: When to start antiretroviral therapy in HIV-infected individuals</i>
3.00pm	Afternoon tea break
3.30pm	Instrumental variable estimation
5.00pm	End of Course



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## Course Preparation

### Getting the most out of pragmatic trials – beyond intention to treat

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- Attendees should have a laptop with R, Stata, or SAS installed
- Instructions on how to install R are attached in a separate document.

#### Course pre-reading:

Murray EJ, Young JG, Swanson S, Robins JM, Hernán MA. *Guidelines for estimating per-protocol effects in pragmatic randomized trials*. Available for download: <https://www.hsph.harvard.edu/causal/pragmatictrials/>

#### Further reading:

- Hernán MA, Robins JM. Per-protocol analyses of pragmatic trials. *New England Journal of Medicine*. 2017;377(14):1391–8
- Murray EJ, Hernán MA. Improved adherence adjustment in the Coronary Drug Project. *Trials*. 2018;19:158
- Murray EJ, Hernán MA. Adherence adjustment in the Coronary Drug Project: A call for better per-protocol effect estimates in randomized trials. *Clinical Trials*. 2016;13(4):372-378
- Murray EJ, Caniglia EC, Swanson S, Hernández-Díaz S, Hernán MA. Patients and investigators prefer measures of absolute risk in subgroups for pragmatic randomized trials. *Journal of Clinical Epidemiology*. 2018;103:10-21.

### Causal inference from observational data: Learning what works

Professor Miguel Hernán

#### Course pre-reading:

Chapters 1-3. Hernán MA, Robins JM (2020). *Causal Inference*. Boca Raton: Chapman & Hall/CRC, forthcoming. Available for free download: <http://www.hsph.harvard.edu/miguel-hernan/causal-inference-book/>

#### Further reading:

- Hernán MA, Robins JM. Using big data to emulate a target trial when a randomized trial is not available. *American Journal of Epidemiology*. 2016;183(8):758-764
- Hernán MA, Sauer BC, Hernández-Díaz S, Platt R, Shrier I. Specifying a target trial prevents immortal time bias and other self-inflicted injuries in observational analyses. *Journal of Clinical Epidemiology*. 2016;79:70-75
- Garcia-Albeniz X, Hsu J, Hernán MA. The value of explicitly emulating a target trial when using real world evidence: an application to colorectal cancer screening. *European Journal of Epidemiology*. 2017;32(6):495-500
- Hernán MA. How to estimate the effect of treatment duration on survival using observational data. *BMJ*. 2018; 360:k182.